UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

HOWMEDICA OSTEONICS CORP.,

OPINION

Plaintiff,

Civ. No. 05-897 (WHW)

ZIMMER, INC.,
CENTERPULSE ORTHOPEDICS, INC.,
(formerly known as SULZER
ORTHOPEDICS, INC.)
and
SMITH & NEPHEW, INC.,

v.

:

Defendants.

Walls, Senior District Judge

Before the Court are plaintiff Howmedica Osteonics Corp.'s ("Howmedica") and defendants Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc.'s motions for claim construction. Defendants also move to strike Dr. Stephen Li's affidavits in support of Howmedica's claim interpretation and Howmedica's supplementary filing of November 13, 2006. Pursuant to Fed. R. Civ. P. 78, the motions are decided without oral arguments.

I. FACTS AND PROCEDURAL BACKGROUND

Howmedica, a New Jersey corporation with its principal place of business in Mahwah,

New Jersey, manufactures and markets medical implants such as artificial knee and hip implants.

Beginning in 1993, Howmedica filed a series of related patents that describe processes for heating and irradiating polymers used in medical implants. See U.S. Patent No. 5, 414,049 (filed Jun. 1, 1993) ("the '049 Patent"); U.S. Patent No. 5,650,485 (filed Oct. 7, 1994) ("the '485 Patent"); U.S. Patent No. 5,543,471 (filed Mar. 15, 1995) ("the '471 Patent"); U.S. Patent No. 5,728,748 (filed Oct. 16, 1996) ("the '748 Patent"); U.S. Patent No. 6,174,934 B1 (filed Jan. 23, 1998) ("the '934 Patent"); U.S. Patent No. 6,372,814 B1 (filed Jun. 28, 2000) ("the '814 Patent"); U.S. Patent No. 6,664,308 B2 (filed Jan. 8, 2002) ("the '308 Patent"); U.S. Patent No. 6,818,020 B2 (filed Jun. 13, 2003) ("the '020 Patent"). The heating processes described in the patents increase the oxidation resistance of medical implants by causing cross-links to form between free radicals produced by the polymer's irradiation. Greater oxidation resistance enables a polymer better to retain its physical properties, making it more suitable for use in medical implants.

Defendants are also corporations that manufacture and market medical implants. In February 2005, Howmedica filed suit against defendants, alleging that they had violated 35 U.S.C. § 271 by infringing four of Howmedica's patents relating to polymeric materials used in medical implants: the '934, '814, '308, and '020 Patents (the "patents-in-suit").

After a period of discovery, the parties moved forward in their litigation. In January 2006, they filed reciprocal Markman motions requesting the Court construe numerous patent claims. In February 2006, defendants filed a motion to exclude affidavits of Howmedica's

¹The '471 Patent is a divisional patent of the original '049 Patent. The four patents asserted by Howmedica here are continuation applications of the '485 Patent, not the '471 Patent.

expert, Dr. Stephen Li, that Howmedica had attached as exhibits to its claim interpretation memoranda. In August 2006, defendants filed a supplemental claim interpretation brief. In November 2006, the Court asked the parties to file additional papers stating which patent claims were potentially at issue and clarifying which terms in those claims required construction. After the parties had filed these supplemental papers, defendants moved to strike Howmedica's clarification. The Court will address each motion in turn.

II. CLAIM CONSTRUCTION

A. STANDARD

Claim construction is a matter of law reserved exclusively for the courts. Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). The claims of the patent-in-suit must be construed before an infringement or invalidity analysis can be performed. Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 149 F.3d 1315 (Fed. Cir. 1998); Helfix, Ltd.v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000). Only those claims at issue and in dispute need to be construed. See United States Surgical Corp. v. Ethicon, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

When interpreting an asserted patent claim, courts should look first to the intrinsic evidence of record, which includes the patent's claims, the patent's specification, and the complete prosecution history. Markman, 52 F.3d at 979. Intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996).

The first principle of claim construction is that "the language of the claim defines the scope of the protected invention." Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp., 55 F.3d 615, 619-20 (Fed. Cir. 1995) (citing Yale Lock Mfg. Co. v. Greenleaf, 117 U.S. 554, 559 (1886). Accordingly, "resort must be had in the first instance to the words of the claim," words to which courts generally ascribe their ordinary meaning. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984). A term's ordinary meaning is the accustomed technical "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." See Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). Claim terms are assigned their ordinary meaning unless it appears from the patent specification or file history that the words were used differently by the inventor. See id. at 1313, 1316-17.

Phillips observed that often "the claims themselves provide substantial guidance as to the meaning of particular claim terms." 415 F.3d at 1314. Both "the context in which a term is used in the asserted claim" and the "[o]ther claims of the patent in question" are useful for understanding the meaning of claim terms. Id. Similarities and differences among various claims are useful for understanding the meaning of particular claim terms. Id. As example, the "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation is not present in the independent claim." Id. at 1314-15 (citing Liebel Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)).

²This direction from the Federal Circuit is one form of what is called <u>claim</u> <u>differentiation</u>, the doctrine that claims should be interpreted to have distinct scopes. The doctrine of claim differentiation is not an absolute doctrine, since clear limitations in the specification may trump a claim's interpretation under claim differentiation. Claim differentiation is most controlling as a hermeneutic aid when a court interprets the relationship

The specification is also highly relevant to the claim construction analysis, especially "when the claim language itself lacks sufficient clarity to ascertain the scope of the claims."

Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc., 347 F.3d 1314, 1324 (Fed. Cir. 2003) (cited in Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1377 (Fed. Cir. 2005)). Often "it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Patent claims "must be read in view of the specification, of which they are a part. . . . For claim construction purposes, the [specification's] description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." Markman, 52 F.3d at 979-80. See United States v. Adams, 383 U.S. 39, 49 (1966); Mycogen Plant Science v. Monsanto Co., 243 F.3d 1316, 1327 (Fed. Cir. 2001); Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). Thus, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

However, in <u>Comark Commc'ns Inc. v. Harris Corp.</u>, the Federal Circuit cautioned that "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitiation into the claim from the specification." 156 F.3d 1182, 1186-87 (Fed. Cir. 1998). If the specification expressly or implicitly defines terms used in the claims differently from their

between independent and dependent claims because the Patent Act instructs that dependent claims "shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." 35 U.S.C. § 112 (emphasis added). See Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006).

ordinary meaning, then the definition derived from the specification will govern how the claim terms are to be interpreted. Markman, 52 F.3d at 979-80. If the embodiments in the specifications are intended to be exemplary, and not "strictly coextensive" with the claims, then they should not be read to limit the claims. See Phillips, 415 F.3d at 1324; Rhine v. Casio, Inc., 183 F.3d 1342, 1346 (Fed. Cir. 1999); Electro Med. Sys. S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

The prosecution history may also aid courts when they construe patent claims. It may demonstrate "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317. If the inventor cites and acquiesces to prior art, this is a good indication of where he understood his claims to begin and end. Autogiro Co. of Am. v. United States, 384 F.2d 391 (1967) (cited in Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1368 (Fed. Cir. 2004)). If the inventor "unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003) (quoted in Liquid Dynamics, 355 F.3d at 1367-68). When an ancestor patent and the patent-in-suit share common claim terms, narrowing disclaimers made during the ancestor patent's prosecution may narrow as well the scope of the common claim terms in the subsequent patent-in-suit. Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 265 F.3d 1294, 1305-06 (Fed. Cir. 2001). See Augustine Med., Inc. v. Gaymar

<u>Indus., Inc.</u>, 181 F.3d 1291, 1300 (Fed.Cir.1999) ("[P]rosecution of a parent application may limit the scope of a later application using the same claim term.").

Courts may also rely on extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980. In particular, technical dictionaries have been recognized as a "tool[] that can assist the court in determining the meaning of particular terminology." Phillips, 415 F.3d at 1318 (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002)). However, extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quotation omitted).

B. ANALYSIS

Howmedica asserts that defendants have infringed twenty-five of its claims. The parties dispute the construction of twelve independent and ten dependent claims.³ The parties have exhaustively briefed their dispute, indentifying numerous discreet terms and phrases whose meaning they dispute. Beyond their disagreement on the meaning of various terms, the parties also contest which words and phrases are in dispute.

Fundamentally, Howmedica and defendants dispute the role the patents' specifications should play in interpreting the language of the disputed claims. Howmedica argues that the

³Howmedica asserts claims 23, 27, 29, 50, and 52 of the '934 Patent; claims 7, 12, and 19 of the '814 Patent; claims 1, 5, 10, 12, 16, 21, 23, and 24 of the '308 Patent; and claims 1, 2, 3, 5, 6, 7, 10, 11, and 12 of the '020 Patent. Howmedica does not ask the Court to construe claims 5 and 16 of the '308 Patent or claim 5 of the '020 Patent.

Court should not import the relatively narrow scope of the invention described by the specification to limit broad claim language. Defendants maintain that the specifications should narrow the scope of facially broad claim language because the specifications implicitly define the disputed claim terms. Ultimately, defendants seek to limit the invention disclosed by the patents-in-suit to the invention described by the preferred embodiment contained in the specifications: a formed and machined polymer implant is put in a package, oxygen is removed from that package, the package is sealed, the package is radiation sterilized and then heated. See, e.g., '934 Patent 6:06-7:38.

In large part, the Court adopts Howmedica's view that defendants seek to improperly import limitations from the specification into the claims. Defendants do not just ask the Court to define claim terms with reference to the specification; they ask the Court to re-draft the disputed claims on the basis of the specification. This is not the task of claim construction.

For economy, the Court will categorize the claims under consideration in this opinion by each issue the parties dispute. Then the Court will determine how each claim should be interpreted with respect to each disputed issue.

With specific exceptions, the Court rejects defendants' arguments that the patent claims at issue require that: (1) the finished orthopedic implant, not constituent polymer material, be irradiated and heated; (2) the irradiation must serve to sterilize the implant; (3) the medical implant must be irradiated and heated after it has been placed in its packaging; and (4) the heating process must have an upper limit of 140° C. To read these claims terms as defendants propose, the Court would have to impermissibly import limitations from the specifications into

the claims. The claims, whose language the patent examiners approved, are unambiguously broader than the particular embodiments of the invention described by the specifications.

Therefore, the Court interprets the specifications to be more exemplary than coextensive of the claims. See Phillips, 415 F.3d at 1324. The prosecution history highlighted by defendants does not convince the Court that Howmedica facilitated the patents' prosecution by limiting the scope of the disputed claim terms, because the ancestor claims' terms differ from the disputed terms.

The Court accepts defendants' arguments that the minimum time and temperature for which the polymer is heated is described by the relationship established by Arrhenius' equation, in those claims which refer to that equation. With respect to the construction of the term "oxidation index" in the '020 Patent, the Court adopts the definition of the term contained in that patent's specification, largely as proposed by defendants.

1. Irradiation and Heating of Polymer / Implant

Defendants contend that the disputed patent claims require that only finished orthopedic components be heated and irradiated. Howmedica argues that the claims also allow for heating and irradiation of pre-formed polymer materials. The Court discerns that this issue potentially arises in all twelve of the independent claims at issue:

- '934 Patent, claim 23: "medical implant comprising an ultra-high molecular weight polyethylene material . . . , said material irradiated . . . and then heated"
- '934 Patent, claim 50: "medical implant comprising a formed olefinic material . . . , said material irradiated . . . and then heated"
- '814 Patent, claim 7: "device comprising an ultra-high molecular weight polyethylene material . . . , said material irradiated . . . and then heated"

- '308 Patent, claim 1: "method of treatment for the ultra-high molecular weight polyethylene material forming a medical implant . . . comprising . . . irradiating . . . and heating the polyethylene material forming the implant"
- '308 Patent, claim 12: "method for processing ultra-high molecular weight polyethylene . . . comprising . . . irradiating . . . and heating the polymer"
- '308 Patent, claim 24: "medical implant comprising . . . an ultra-high molecular weight polyethylene material . . . , said material . . . which has been irradiated . . . and then heated"
- '020 Patent claim 1, 6: "medical implant comprising an irradiated ultra-high molecular weight polyethylene"
- '020 Patent, claims 7, 10, 11, 12: "medical implant comprising an ultra-high molecular weight polyethylene . . . irradiated and annealed"

Defendants argue that the scope of the above claims should be limited to medical implants or devices, which are irradiated and heated <u>after</u> they have been formed and/or machined.

Howmedica argues that these claims also encompass processes whereby a polyethylene material is irradiated and heated before it is formed and/or machined into a medical implant.

Howmedica relies upon the language of the patent claims for its interpretation.

Defendants support their construction by arguing that the four patents' specifications limit the patent claims. Because the specifications only expressly set forth a process whereby fully finished orthopedic components are irradiated and heated, defendants maintain that the claims should be limited to that process.

a. '934 Patent, claims 23, 50; '814 Patent, claim 7; '308 Patent, claims 12, 24; '020 Patent, claims 1, 6

Claims 23 and 50 of the '934 Patent, claim 7 of the '814 Patent, claims 12 and 24 of the '308 Patent, and claims 1 and 6 of the '020 Patent clearly and unambiguously contemplate

each of these claims by looking towards its ordinary meaning, grammar, syntax, and context. To narrowly construe these claims, whose language unequivocally establishes their meaning, would be to commit the "cardinal sin" of claim construction: to import limitations from the specification into the claim. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340 (Fed. Cir. 2001). In contrast, the express language of claim 1 of the '308 Patent clearly limits that claim to irradiation and heating of finally formed medical implants.

Claims 23 and 50 of the '934 Patent, claim 7 of the '814 Patent, and claim 24 of the '308 Patent all distinguish between (1) the "implant" or "device" and (2) the "material." These four claims unambiguously refer to the irradiation and heating of "said material"; they do not refer to the treatment of the "implant" or "device." Had the inventor intended to limit the scope of these claims to the heat and radiation treatment of "finished orthopedic implants," he would have stated that the implant, not the "material," was to be irradiated and heated. The Court reads these claims to include the treatment of the constituent polyethylene material <u>before</u> it has been formed and machined into its final form as an implant.

Claim 12 of the '308 Patent expressly states that it is for a "method of processing . . . polyethylene." Never does claim 12 refer to processing a medical implant, finished or unfinished. It clearly describes a method of heating and irradiating a "polymer," and is not limited to the treatment of finished implants.⁴

⁴This is especially clear when the language of claim 12 of the '308 Patent is juxtaposed with claim 1 of that Patent, which is so limited. See infra.

Claims 1 and 6 of the '020 Patent refer to a medical implant comprised of "an irradiated ultra-high molecular weight polyethylene." The Court finds that this claim clearly expresses that the polyethylene is irradiated, and imposes no requirement that the irradiation step occur after the medical implant has been finished.

b. '308 Patent, claim 1

In constrast, the Court finds that claim 1 of the '308 Patent is limited to irradiation and heating of a finished implant, because it is for "irradiating . . . and heating the polyethylene material forming the implant." Claim 1 clearly contemplates that the polyethylene material has already been formed into an implant <u>before</u> it is irradiated and heated. The Court's interpretation is bolstered by comparing claim 1 to claim 12 of the '308 Patent, which describes a process identical to that described by claim 1 – except that it refers to the irradiation of the "polymer" and not the finished implant.⁵

c. '020 Patent, claims 7, 10, 11, 12

Unlike the '934, '814, '308, and '020 Patent claims discussed above, claims 7, 10, 11, and 12 of the '020 Patent are ambiguously phrased. These latter claims describe a "medical implant comprising an ultra-high molecular weight polyethylene . . . irradiated and annealed." It is not grammatically clear if these claims could involve irradiating and heating the polyethylene

⁵Unless otherwise stated, the dependent claims at issue are construed in accord with this opinion's reading of the respective independent claims. As example, claims 27, 29, and 52 of the '934 Patent, claim 12 of the '814 Patent, claims 21 and 23 of the '308 Patent, and claims 2, 3, and 5 of the '020 Patent are not limited to the processing of finished implants. Dependent claim 10 of the '308 Patent is limited to the irradiation and heating of the finished implant.

material, or if they are limited to treating finished implants made of the material. From the claims alone, the Court cannot discern whether the "medical implant" or the "polyethylene" are modified by the term "irradiated and annealed."

Faced by ambiguous claim language, the Court looks to the context of these claims. The Court has already determined that claims 1 and 6 of the '020 Patent do not require that only the finished implant may be irradiated. See supra. Claims 7, 10, 11, and 12 are clearly intended to parallel claims 1 and 6, which the Court has construed to disclose heat and radiation treatment of both the polymer and finished implants. Notably, claims 7, 10, 11, and 12 include an annealing (heating) step that makes their grammar and syntax more ambiguous. As example, claim 1 describes a "medical implant comprising an irradiated ultra-high molecular weight polyethylene," while claim 7 describes a "medical implant comprising an ultra-high molecular weight polyethylene . . . irradiated and annealed." Since the only material difference between the two sets of claims is the annealing step, the Court interprets claims 7, 10, 11, and 12 of the '020 Patent consistently with claims 1 and 6. Claims 7, 10, 11, and 12 of the '020 Patent are not limited to the irradiation and annealing of finished implants.

d. Prosecution History

The Court finds unconvincing the Defendants' reference to the prosecution of the '049, '748 and '020 Patents. Defendants seek to limit terms of the patents-in-suit by pointing to limitations made during the course of the prosecution of the '049 Patent, an ancestor patent of the patents-in-suit. Unlike the '934, '814, '308, and '020 Patents, all of the '049 Patent's claims clearly describe a process whereby a finished implant is irradiated and heated. The '049 Patent

does not share the relevant claim terms with the patents-in-suit. <u>See Advanced Cardiovascular</u>, 265 F.3d at 1305-06. As example, a typical claim of the '049 Patent states:

A method for producing a medical implant . . . comprising the steps of: sealing the implant in an oxygen impermeable package . . . ; and radiation sterilizing the said packaged implant; and heating said packaged implant . . . at a temperature of between about 37 C and the melting point of [the] olefenic material 6

'049 Patent, claim 1. Unlike the patents disputed here, all the '049 Patent claims clearly and unambiguously refer to a process where the <u>finished</u>, <u>packaged implant</u> is irradiated and heated. The Court will not limit the scope of the descendant patents on the basis of representations made during the prosecution of the ancestor patents, when the ancestor patent's claims differ so materially from those of the descendant patent.

Defendants also cite Howmedica's communications to the examiner during its prosecution of the '020 and '748 Patents. Neither of these statements is particularly relevant here. At the examiner's request, Howmedica cancelled certain patent claims "directed to an ultra-high molecular weight polyethylene." (See Defs.' Exs. J, K.) Contrary to defendants' assertions, Howmedica's did not restrict the invention to irradiation and heat treatment of formed medical implants. The '748 Patent prosecution statements to which defendants point, which sought to distinguish that patent from prior art, are not properly characterized as disclaimers.

⁶All of the independent claim in the '049 Patent are similar in that they expressly describe irradiating and heating a finished, packaged implant. '049 Patent, claims 1, 12, 19, 25, 31, 36.

(See Defs.' Ex. N.) By no means do they clearly disclaim the treatment of the polymer before it is formed.

2. Construction of "Irradiate"

Defendants argue that the irradiation step described in the patent claims at issue requires irradiation for the purposes of sterilization. Howmedica argues that the irradiation step may also include irradiation which is not for the purposes of sterilization.

- '934 Patent, claims 23, 50; '814 Patent, claim 7: "said material irradiated to create free radicals"
- <u>'814 Patent, claim 19</u>: "irradiating said material . . . to create free radicals"
- <u>'308 Patent, claim 1</u>: "irradiating the polyethylene material forming said implant to create free radicals"
- <u>'308 Patent, claim 12</u>: "creating free radicals in the polymer chain by irradiating the ultrahigh molecular weight polyethylene material"
- '308 Patent, claim 24: "said material . . . which has been irradiated to create free radicals"
- '020 Patent, claims 1, 6: "irradiated ultra-high molecular weight polyethylene"
- <u>'020 Patent, claims 7, 10, 11, 12</u>: "ultra-high molecular weight polyethylene . . . irradiated"

Howmedica proposes that "irradiated" means "is exposed to radiation, including but not limited to gamma ray, x-ray or electron beam radiation." Defendants propose that the term "irradiated" means "sterilization irradiated, *i.e.* exposed to radiation for purposes of sterilization."

Defendants seek to narrow the term's meaning by referring to the predominant (but not exclusive) usage of the term irradiation in the specifications: irradiation "for purposes of sterilization." The Court rejects defendants' argument.

a. '934 Patent, claims 23, 50; '814 Patent, claims 7, 19; '308 Patent, claims 1, 12, 24

The ordinary meaning of the term "irradiate," without modification, does not inherently connote "irradiate for the purpose of sterilization." Irradiate means to expose to radiation, plain and simple.

Express limitations in related dependent claims also do not support defendants' narrow definition of the term "irradiated" in claims 23 and 50 of the '934 Patent. Dependent claim 28 of the '934 expressly limits independent claim 23 to radiation treatment of sufficient strength and type to sterilize the polymer: it is for "[t]he medical implant as set forth in claim 23 wherein the irradiation is a high energy beam of a dose capable of killing bacteria, viruses, or other microbial species." '934 Patent, claim 28. The limitation in the dependent claim strongly implies that "irradiated" in claim 23 includes exposure to radiation insufficient or inappropriate to sterilize the material. See Phillips, 415 F.3d at 1314-15 ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation is not present in the independent claim"). Accordingly, the Court interprets the term "irradiated" in claims 50 of the '934 Patent consistently with claim 23, that is, to mean "exposed to radiation." Such meaning includes, but is not limited to, "sterilization irradiation."

In addition, claims 23 and 50 of the '934 Patent, claims 7 and 19 of the '814 Patent, and claims 1, 12 and 24 of the '308 Patent all state that the claim requires the material to be irradiated "to create free radicals" or that the claim is for a method for "creating free radicals . . . by irradiating" the material. Since the express purpose of the irradiation process described by the

claims is the production of free radicals, not sterilization, the claims themselves do not support defendants effort to limit the process to "sterilization irradiation." The Court finds that the meaning of the term "irradiation" is consistent throughout the '934, '814, and '308 Patents: "irradiate" is not limited to "sterilization irradiate."

b. '020 Patent, claims 1, 6, 7, 10, 11, 12

The term "irradiated" in claims 1, 6, 7, 10, 11, and 12 of the '020 Patent is not clearly defined by the context of the other claims of that Patent. Though, as defendants point out, the '020 Patent's specification contemplates the process of irradiating the polymer material solely in the context of sterilization, '020 Patent, 3:40-7:37, the Court does not conclude that the specification is intended by the inventor to <u>define</u> "irradiation" only as "sterilization irradiation." Because the other, related patents used the term "irradiated" more broadly than "sterilization irradiation," the Court will give the term its ordinary, broader meaning in the '020 Patent as well. <u>See Inline Connection Corp. v. AOL Time Warner Inc.</u>, 302 F. Supp. 2d 307, 324 (D. Del. 2004) (construing term "tranceiver" uniformly, as having broad ordinary meaning, through entire patent family). In all of the claims at issue, the Court interprets "irradiated" to carry its ordinary meaning: "exposed to radiation."

3. Method of Segregation from Oxygen During Irradiation and Heating Steps

⁷The Court rejects Defendants attempt to use the prosecution histories of the '049 and '748 Patents to limit the disputed claims to sterilization radiation for the reasons recited above. The '049 Patent contains distinct claim terms, and the '748 Patent communication does not amount to a clear limitation of "radiation" to "sterilization irradiation."

Defendants argue that the patent claims require the irradiation and heating steps of the process to occur in an airtight package.⁸ Howmedica argues that the patent claims allow these steps to occur in some other type of reduced-oxygen environment.

a. heated "out of contact with oxygen"

Seven of the claims at issue state that the material being processed is kept "out of contact with oxygen:"9

- <u>'934 Patent, claims 23, 50; '814 Patent, claim 7</u>: "said material irradiated . . . and then heated while out of contact with oxygen in a concentration greater than 1% volume by volume"
- <u>'814 Patent, claim 19</u>: "irradiating . . . and annealing said material while out of contact with oxygen in a concentration greater than 1% volume by volume"
- <u>'308 Patent, claim 1</u>: "irradiating . . . and heating the polyethylene material forming the implant . . . while said polyethylene material is prevented from contact with oxygen in a concentration greater than 1% volume by volume"
- <u>'308 Patent, claim 12</u>: "creating free radicals in the polymer chain by irradiating the ultrahigh molecular weight polyethylene material [and] preventing oxygen from bonding with the said created free radicals by preventing them from coming into contact with oxygen in a concentration greater than 1% volume by volume . . . and heating the polymer . . . prior to exposing the free radicals to oxygen above the said concentration"
- <u>'308 Patent, claim 24</u>: "ultra high molecular weight polyethylene material . . . which has been irradiated . . . and then heated while out of contact with oxygen in a concentration greater than 1% volume by volume"

⁸As mentioned, defendants construe the patents-in-suit to disclose only a process whereby the finished implant is enclosed in its final package, and is then the package is irradiated and heated. This is the process described in the preferred embodiment. Accordingly, defendants use the term "package" to refer to a packaging material which surrounds a finished implant.

⁹Five claims, which the Court will discuss later, state that the material is surrounded by a "layer of material" that prevents contact with oxygen when heated.

Howmedica argues that the Court should interpret "while out of contact with oxygen in a concentration greater than 1% volume by volume" as "without the UHMWPE [ultra-high molecular weight polyethylene] material contacting the surrounding atmosphere that contains oxygen in a concentration greater than 1% volume by volume." Defendants argue that "while out of contact with oxygen in a concentration greater than 1% volume by volume" means "in an airtight package with less than 1% oxygen by volume." Defendants refer to the process described in the summary of the invention and the preferred embodiment in the specification to narrow the scope of the invention. The Court rejects defendants' argument.

Defendants point out that the specifications only describe a process whereby the implant is irradiated and heated after it is placed in a package from which the oxygen is expelled.

Nevertheless, the Court does not find that the specification was intended to implicitly limit the meaning of "while out of contact with oxygen in a concentration greater than 1% volume by volume" to "in an airtight package." In the context of other claims in the patents, the claims at issue clearly intend a broader meaning for "out of contact with oxygen" than "in an airtight package," and so the Court will give the term the broader meaning.

i. '934 Patent, claims 23, 50

Related dependent claims do not support defendants' definition of the phrase "while out of contact with oxygen in a concentration greater than 1% volume by volume" in independent claim 23 of the '934 Patent. Dependent claim 33 is for "[t]he medical implant as set forth in claim 23 wherein an oxygen impermeable packaging material is the layer used to prevent the polyethylene material from contacting oxygen." '934 Patent, claim 33. The Court will not read a limitation

expressly stated in the dependent claim (claim 33) into an independent claim that does not contain that limitation (claim 23). See Phillips, 415 F.3d at 1314-15. The limitation in dependent claim 33 implies that "while out of contact with oxygen in a concentration greater than 1% volume by volume" in claim 23 of the '934 Patent is intended to contemplate methods of segregating the material from oxygen that do not involve "oxygen impermeable packaging materials."

Similarly, dependent claim 55 of the '934 Patent limits the device set forth in claim 50 to processes whereby an "oxygen impermeable packaging material" is used to prevent contact with oxygen. The Court finds that the irradiation and heating steps described in claims 23 and 50 of the '934 Patent are not limited to heating and irradiation "in an airtight package"--unlike the processes described by dependent claims 33 and 55, which are so limited.

ii. '308 Patent, claims 1, 12

Identical logic dictates that independent claims 1 and 12 of the '308 Patent are not limited to heating and irradiating the polyethylene "in an airtight package." Dependent claims 2 and 3 of the '308 Patent are for the method set forth in independent claim 1, but specify that the process takes place in an oxygen impermeable packaging material:

- 2. The method set forth in claim 1, wherein the contact with oxygen is prevented by sealing the polyethylene within an oxygen impermeable barrier.
- 3. The method as set forth in claim 2, wherein the oxygen impermeable barrier is a packaging material.

'308 Patent, claims 2, 3. Once again, the Court will not read the limits expressly stated in the dependent claims (i.e. claims 2 and 3) into the independent claim (i.e. claim 1). See Phillips, 415

F.3d at 1314-15. Dependent claims 13 and 14 of the '308 Patent similarly limit the process described in claim 12, and the express limits of the former claims should not be imported into the latter. Accordingly, the Court finds that claims 1 and 12 of the '308 Patent are not limited to a process whereby the polymer is heated and irradiated "in an airtight package."

iii. '308 Patent, claim 24

Claim 24 of the '308 Patent contains language which is very similar to that of claims 1 and 12 of that patent. In general, similar terms in different claims should be construed consistently.

See Phillips, 415 F.3d at 1314 ("usage of a term in one claim can often illuminate the meaning of the same term in other claims"). The Court construes "heated while out of contact with oxygen" in claim 24 of the '308 Patent consistently with "heating . . . while . . . prevented from contact with oxygen" in claim 1 of the '308 Patent. In addition, the language of claim 24 of the '308 Patent is nearly identical to the language of claims 23 and 50 of the '934 Patent and claim 7 of the '814 Patent, which the Court has already found do not require segregation "in an airtight package." Claim 24 of the '308 Patent does not require segregation from oxygen "in an airtight package."

iv. '814 Patent, claims 7, 19

Independent claim 19 of the '814 Patent does not require an "airtight package" to surround the material during the irradiation and heating steps. Unlike claim 19, dependent claim 20 of the '814 Patent refers to an "oxygen impermeable barrier around [the polyethylene material] prior to irradiating." Because a court should not read express limitations from dependent claims into

independent claim's that lack that limitation, "while out of contact with oxygen" in claim 19 should not be limited to claim 20's "[surrounded by an] oxygen impermeable barrier."

Accordingly, the Court will not limit the term "while out of contact with oxygen" in claim 19 to "in an airtight package," the even narrower construction that defendants urge for the claim.

The Court construes "while out of contact with oxygen" in claim 7 of the '814 Patent consistently with the term's use in claim 19. Neither claim requires that the heating step occur "in an airtight package."

b. "surrounded by a layer of material"

As the Court has noted, five of the claims at issue state that the polymer material is processed while surrounded by a layer of material that prevents contact with oxygen:

- '934 Patent, claims 29, 52: "material is surrounded by a layer of material whose function is to prevent said . . . material from contact with oxygen and said layer is heated"
- <u>'814 Patent, claim 12</u>: "device as set forth in claim 7 wherein a layer of material is provided to prevent said polyethylene material from coming into contact with oxygen"
- '308 Patent, claim 10: "polyethylene implant material is surrounded by a layer of material whose function is to prevent said polyethylene material from coming into contact with oxygen, said layer of material is heated"
- <u>'308 Patent, claim 21</u>: "polyethylene is surrounded by a layer of material whose function is to prevent said polyethylene material from said contact with oxygen, said layer of material is heated"

The ordinary meaning of these claim terms is narrower than the seven claims the Court examined earlier, which merely involved an unspecified method of isolation from oxygen. However, the Court's analysis of these claims is similar to the analysis it employed earlier.

i. '934 Patent, claims 29, 52

The Court finds that claims 29 and 52 of the '934 Patent, which specify that the polymer is segregated from oxygen by a layer of material, are not limited to processes that segregate the polymer from oxygen by a packaging material. This is because the doctrine of claim differentiation suggests that when two distinct claims depend from one independent claim, they should not be read to place the same limitations on that independent claim. Otherwise the dependent claims would render one another superfluous.

Claims 29 and 33 both depend from independent claim 23 of the '934 Patent, but limit claim 23 differently. Dependent claim 29 limits claim 23 of the '934 Patent to processes whereby the polymer "is surrounded by a layer of material" to segregate from oxygen. In contrast, dependent claim 33 of the '934 Patent limits dependent claim 23 to processes whereby an "oxygen impermeable packaging material is the layer used to prevent the polyethylene material from contacting oxygen." The doctrine of claim differentiation strongly suggests that claim 29 is distinct from, and broader than, claim 33.

Similarly, claims 55 and 52 both depend from independent claim 50 of the '934 Patent.

Dependent claim 55 of the '934 Patent limits independent claim 50 to processes wherein an "oxygen impermeable packaging material is used to prevent the olefinic material from contacting oxygen," while dependent claim 52 of the '934 Patent only limits claim 50 to processes whereby the polymer is segregated from oxygen by "a layer of material." This implies that claim 52 is broader in scope than claim 55.

The Court therefore finds that claims 29 and 52 of the '934 Patent, unlike claims 33 and 55, are not limited to processes whereby the polymer is isolated from oxygen by an airtight package.

ii. '308 Patent, claims 10, 21

Applying identical reasoning, the Court finds claims 10 and 21 of the '308 Patent, which specify that the polymer is segregated from oxygen by a "layer of material," are not limited to using an airtight package to prevent the polymer from contacting oxygen.

Claims 3 and 10 both depend from independent claim 1 of the 308 Patent. Dependent claim 3 of the '308 Patent expressly limits independent claims 1 of that patent to processes wherein the method for preventing the polyethylene material's contact with oxygen is "a packaging material." In contrast, dependent claim 10 limits claim 1 of that patent to processes whereby "a layer of material" prevents the polyethylene material's contact with oxygen. The doctrine of claim differentiation suggests that the language of claim 10 is intended to convey a broader scope for that claim than the precise and narrow language of claim 3 of the '308 Patent.

Dependent claims 21 and 14 both depend from independent claim 12 of the '308 Patent.

Dependent claim 14 of the '308 patent expressly limits independent claim 12 of the '308 Patent to processes whereby the method for preventing the polyethylene material's contact with oxygen is "a packaging material." This implies that claim 21, which specifies that a "layer of material" segregates the polymer from oxygen, is intended to be broader in scope than the narrowly defined claim 14 of the '308 Patent.

Neither claim 10 nor claim 21 of the '308 Patent require the polymer be heated "in an airtight package." In other words, the material used to segregate the polymer from oxygen does not have to be a packaging material.

iii. '814 Patent, claim 12

The meaning of "layer of material" in claim 12 of the '814 Patent is not so easily construed in the context of that patent's other, related claims. Even so, the Court will not interpret the term to require the polyethylene material be isolated from oxygen by an airtight package. First, the language of claim 20, referring to an "oxygen impermeable barrier around said material," suggests that "layer of material" is distinct from and broader than "in an airtight package." Second, because the related '934 and '308 Patents used the term "layer of material" more broadly than "an airtight package," the Court will not narrow the term merely on the basis of a specification that does not clearly limit the invention to the embodiment. See Inline Connection Corp. v. AOL Time Warner Inc., 302 F. Supp. 2d 307, 324 (D. Del. 2004). The Court interprets "layer of material" to mean exactly what it says and no more. The phrase does not restrict claim 12 to sterilization and heating "an airtight package."

4. Temperature Range of the Heating Step of Processing

Defendants argue that the claims at issue require that the heating stage of the process must occur at a temperature between 25°C and a specified upper limit. Howmedica asserts that the claims do not specify an upper temperature limit for the heating stage.

'934 Patent, claims 23, 50; '814 Patent, claim 7; '308 Patent, claim 24: "said material . . . heated . . . at a temperature . . . greater than 25°C"

- '814 Patent, claim 19: "annealing said material . . . at a temperature greater than 25°C"
- '308 Patent, claims 1, 12: "heating the [polyethylene material/polymer]"
- '308 Patent, claims 5, 16: "method as set forth in claim [1/12], wherein the temperature is greater than 25°C"
- <u>'020 Patent, claims 10, 11, 12</u>: "medical implant comprising an ultra-high molecular weight polyethylene . . . annealed at a temperature of greater than 25°C"

Howmedica proposes that the phrase "at a temperature [...] greater than 25°C" requires no interpretation. Defendants argue that the Court should interpret this phrase as "at a temperature of greater than 25°C but less than 140°C." Defendants refer to the summary of the invention and the preferred embodiment in the specification to narrow the scope of the claim. They observe that the process described in the specification does not include situations wherein the material is heated at a temperature greater than its melting point. The Court rejects defendants' argument.

a. "heating" / "heating at a . . . temperature greater than 25°C"

i. '934 Patent, claims 23, 50

Related dependent claims do not support defendants' proposed limitation of the ordinary meaning of the terms "heating" and heating "at a temperature [...] greater than 25°C" in independent claims 23 and 50 of the '934 Patent. Dependant claims 30 and 53 of the '934 Patent are for "[t]he medical implant... wherein said heating has an upper temperature limit of the melting point of the ... material." '934 Patent, claims 30, 53. Dependent claims 32 and 54 are

¹⁰ The description of the preferred embodiments indicates that the melting point or distortion temperature of ultra-high molecular weight polyethylene is "about 140°C." See, e.g., '934 Patent, 5:55-58; 6:66-7:02.

for "[t]he medical implant . . . wherein said heating has an upper limit not exceeding the distortion temperature of the . . . material." '934 Patent, claims 32, 54. In contrast, independent claims 23 and 50 of the '934 Patent do not specify any upper temperature limit on the heating process. The express upper temperature limits in the four dependent claims imply that heating "at a temperature . . . greater than 25°C," without any express upper limits, includes processes whereby the material is heated above its melting or distortion point, approximately 140°C. See Phillips, 415 F.3d at 1314-15 (express limitations in dependent claims should not be read into independent claims). The Court finds that the heating processes described by claims 23 and 50 of the '934 Patent are not limited to an upper temperature of 140°C.

ii. '814 Patent, claim 7

Limitations on a related dependant claim also imply that "heated . . . at a temperature . . . greater than 25 C" in claim 7 of the 814 Patent does not disclose an upper limit on the heating of the polymer. Dependent claim 10 of the '814 Patent is for "[t]he device . . . wherein the polyethylene material is heated to a temperature between 25°C and the melting point of said polymer," which implies that independent claim 7 of the '814 Patent is not so limited because it specifies no upper temperature limitation. See Phillips, 415 F.3d at 1314-15. The Court finds that claim 7 of the '814 Patent does not place an upper temperature limit of 140°C on the heating process.

iii. '308 Patent, claims 1, 5, 12, 16, 24

Likewise, limitations on a related dependant claim imply that the disputed claims of the 308 Patent do not disclose an upper limit on the heating of the polymer. Dependent claims 9 and 20 of the '308 Patent are for "the method . . . wherein the polyethylene material is heated to a temperature . . . between 25°C and the melting point of said polymer." '308 Patent, claims 9 and 20. The limitations established in all of these dependent claims lead the Court to find that independent claims 1 and 12 of the '308 Patent, which only specify "heating the polyethylene material," may include processes whereby the material is heated above 140°C. See Phillips, 415 F.3d at 1314-15. Claims 5 and 16 of the '308 Patent limit the invention described in claims 1 and 12 to processes "wherein the temperature is greater than 25°C," but do not specify any upper limit. '308 Patent, claims 5, 16. Applying the doctrine of claim differentiation, the Court finds that claims 5 and 16 include processes that involve heating the polymer to a temperature greater than 140°C.

Claim 24 of the '308 Patent specifies that the material is heated at a "temperature of greater than 25°C." '308 Patent, claim 24. Reading the language of claim 24 consistently with claims 5 and 16, the Court finds that claim 24 of the '308 Patent is not limited to heating at a temperature of less than 140°C.

b. "annealed at a temperature of greater than 25°C"

i. '020 Patent, claims 10, 11, 12

The language of the '020 Patent claims is less clear because the context does not clarify the definition of the claims at issue. Also, the '020 Patent claims differ from those of the other

patents because they use the word "anneal" rather than "heat." The Court will not base its interpretation of these claims on its construction of the '934, '814, and '308 Patents, and will look to the specification to define the term "anneal" in the '020 Patent claims. The '020 Patent specification only describes an annealing process which takes place at a temperature between 25°C and 140°C. This confirms the Court's understanding of the plain language definition of the term "anneal," which is method of changing a material's physical properties by heating a material to a point below its melting point and then cooling that material. The Court will interpret "annealed at a temperature of greater than 25°C" in claims 10, 11, and 12 of the '020 Patent to mean exactly that: "annealed at a temperature of greater than 25°C" and less than the melting point of that material – approximately 140°C.

ii. '814 Patent, claim 19

Claim 19 of the '814 Patent similarly states that the method of treatment consists of "annealing said material . . . at a temperature greater than 25°C," unlike the other disputed claims of that patent, which disclose the "heating" of the material. Looking towards the ordinary meaning and the specification, the Court finds that claim 19 of the '814 Patent describes a process of heating the material to a temperature between 25°C and 140°C.

c. Prosecution History

The Court rejects Defendants' resort to the prosecution histories of the '934, '471, and '485 Patents because the prosecution history does not demonstrate that Howmedica limited the upper temperature of the heating stage in response to the examiner's objections. In amending its

'934 Patent, Howmedica did not add an upper temperature limit; Howmedica lowered the lower temperature limit. In his objection to the '471 and '934 Patent claims, the examiner was objecting to the claims' highly imprecise temperature and duration language, not to the lack of an upper temperature limit of 140°C.

5. Relationship of Duration of Heating Step to Its Temperature

'934 Patent, claims 23, 50; '814 Patent, claims 7, 19; '308 Patent, claim 1, 12, 24: heating material at a temperature and for a time at least equivalent to heating "at 50°C for 144 hours as defined by . . . Arrhennius' [sic] equation (14)."

The 9 claims at issue here require the heating of the material at a temperature and for a period at least equivalent to heating the material "at 50°C for 144 hours as defined by . . .

Arrhennius' equation (14)." Defendants argue that this phrase needs no construction. But, they add, should the Court decide to interpret the phrase, it means "as defined by equation 14 from the patent specification." In its original claim construction brief, Howmedica argued that Arrhenius' equation, in the case of ultra-high molecular weight polyethylene, should be construed as dictating that for every 10°C increase of the heating temperature the required duration of heating is halved. ¹² In its supplementary filing of November 2006, Howmedica does not offer any

¹¹Arrhenius' equation, named after the Swedish chemist Svante August Arrhenius, which will be discussed in greater detail below, expresses a mathematical relationship between the reaction temperature and the rate at which a reaction occurs. <u>See</u> '934 Patent, 6:55-6:65.

¹² Claim 23 calls for the ultra-high molecular weight polyethylene to be heated for 144 hours at 50°C, or the equivalent thereof according to Arrhenius' equation. Under Howmedica's simplified construction, as example, the polyethylene may be heated for 72 hours at 60°C, or for 36 hours at 70°C.

construction of this term, implying that there is no need for construction.¹³ The Court agrees that construction of this phrase is not required at this time, because it clearly refers to Arrhenius' equation as it is defined by equation 14 in the '934, '814, and '308 Patent specifications. See, e.g., '934 Patent, 6:58.

6. Construction of "Oxidation Index"

Howmedica argues that the Court should construe this term to mean "a relative measurement of the amount of oxidized material present in the UHMWPE." Defendants propose that oxidation index should be read to mean "the area of the IR absorbtion peaks in the frequency range of between 1660 and 1800/cm divided by the area of the 1463/cm peak."

- '020 Patent, claim 3: "the polyethylene has an FTIR . . . oxidation index which does not increase with oven aging in air . . ."
- '020 Patent, claims 6, 10: "polyethylene having . . . an oxidation index which does not increase during oven aging in air"
- '020 Patent, claim 7: "polyethylene having . . . a non-increasing FTIR oxidation index during oven aging in air"
- '020 Patent, claim 11: "polyethylene . . . irradiated and annealed . . . for a sufficient time to have an non-inreasing FTIR oxidation index of .01 during oven aging in air"
- '020 Patent, claim 12: "polyethylene . . . irradiated and annealed . . . for a sufficient time to have an non-inreasing FTIR oxidation index of .01 or less during oven aging in air"

¹³In its subsequent opposition to Zimmer's motion for summary judgment, Howmedica relies on expert declarations to oppose Zimmer's position that this term is invalid for indefiniteness. One of these expert declarations expressly contradicts Howmedica's initial position here, i.e. that the Arrhenius equation is construable as a simple relationship halving the duration of heating for every 10°C increase. (Howmedica Opp'n to Summary Judgment, Risen Decl. at 7.)

The meaning of this term is impossible to derive from the language of the claim itself, nor is the ordinary meaning of this term apparent to the Court. Howmedica's sole foundation for its interpretation is Dr. Stephen Li's conclusory assertion of what a person of the ordinary skill in the art would understand "oxidation index" to mean.

In contrast, to support their construction, defendants point to the sole occasion in which the term "oxidation index" appears in the '020 Patent specification. The term appears in the context of an involved description of how the oxidation index for a particular set of materials was obtained:

Two sets of 1-mm-thick UHMWPE sheets prepared by Methods A through D above were oven aged in air at 80°C for 11 and 23 days respectively. After these sheets were cooled in room temperature, a thin film specimen of about 100 microns in thickness was cut from each of the 1-mm-thick aged UHMWPE sheets and placed in an IR window for a standard FTIR (A Nicolet 710 FTIR system was used) transmission run. A total of 32 spectra (scans) was collected and averaged. To determine the extent of oxidation, the IR absorption peaks in the frequency range of between 1660 and 1800 cm⁻¹, corresponding to carbonyl (C--O) functional groups, were integrated for the peak area. The peak area is proportional to the amount of oxidized UHMWPE in the specimen. To correct for difference in specimen thickness, the integrated peak area was then normalized to the specimen thickness, by dividing by the area of the 1463 cm⁻¹ (methyl) peak which is proportional to the specimen thickness. The obtained ratio was defined as oxidation index.

'020 Patent 7:63-8:13 (emphasis added). This portion of the specification expressly defines the term "oxidation index" to mean a ratio which is derived from the spectroscopic measurements described by the specification. When the specification gives a special definition to a term, that definition trumps the ordinary meaning of that term. See Phillips, 415 F.3d at 1316; CCS Fitness,

<u>Inc. v. Brunswick Corp.</u>, 288 F.3d 1359, 1366 (Fed. Cir. 2002); <u>Markman</u>, 52 F.3d at 979-80.

Accordingly, the Court adopts the definition of "oxidation index" expressed by the specification.¹⁴

III. DEFENDANTS' MOTION TO STRIKE TESTIMONY OF DR. LI

In support of its claim construction memoranda, Howmedica filed two declarations by Dr. Stephen Li. Howmedica characterizes these two documents as declarations by a person of the ordinary skill in the art. Defendants characterize Dr. Li's declarations as expert testimony subject to the admissibility standards of Federal Rule of Evidence 702. Defendants assert that under Rule 702's standards the Court should strike Dr. Li's declarations as inadmissible.

The Court is mindful of the Federal Circuit direction that district courts look first towards intrinsic evidence when they construe patent claims. Markman, 52 F.3d at 979. As this Court has noted in a previous patent decision, it is wary of the reliability of expert evidence produced solely for the purposes of claim construction. Ricoh Co., Ltd. v. Katun Corp., 380 F.Supp.2d 418, 423 (D.N.J. 2005); Vitronics, 90 F.3d at 1584. This is particularly so when the expert testimony is largely conclusory in its assertions – as Dr. Li's declarations are. Phillips, 415 F.3d at 1318.¹⁵

¹⁴To the extent that defendants' proposed definition accurately conveys the process for obtaining an oxidation index for UHMWPE material, the Court adopts that definition. If the parties further contest the construction of this term, additional briefing and/or arguments may be required.

¹⁵Troublingly, Dr. Li's declarations often state how a person of the ordinary skill in the art would interpret a term, without furnishing (1) sufficient rationale for the Court to evaluate that construction and (2) any indication of how Dr. Li defines such a person. Implicitly, Dr. Li relies upon his own understanding of a term to arrive at the construction a person of the ordinary skill in the art would endorse.

The Court relied solely on the intrinsic evidence in the patent record to construe the claims at issue here. Since the Court did not ultimately rely on Dr. Li's declarations for its construction, it will not unnecessarily determine whether they are admissible.

IV. DEFENDANTS' MOTION TO STRIKE HOWMEDICA'S SUPPLEMENTAL FILING OF NOVEMBER 2006

Defendants also move to strike Howmedica's supplemental filing of November 13, 2006. First, they argue that Howmedica represented to the Court, during an October 23, 2006 conference call, that only ten claims required construction. Second, they argue that Howmedica used its filing, which the Court had requested to clarify the parties' claim construction dispute, to advance novel interpretations of various claims. Defendants cite no controlling legal authority for their motion. The Court sees no merit in either of defendants' arguments because it disagrees with defendants' factual assertions.

Howmedica represented that it would ask the Court to construe approximately ten independent claims. Its supplemental filing asks the Court to construe twelve independent claims. Howmedica's supplementary filing is largely consistent with its earlier filings. Where variations exists, they are minor and ultimately immaterial to the Court's construction.

The Court will not strike the Howmedica's supplemental claim construction filing.

V. CONCLUSION

It is on this 23rd day of April, 2007:

ORDERED that parties' motions for claim construction are decided as set forth by this opinion;

ORDERED that defendants' motion to strike the declarations of Dr. Stephen Li is DENIED; and

ORDERED that defendants' motion to strike Howmedica's supplemental filing of November 2006 is DENIED.

s/ William H. Walls

United States Senior District Judge